

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

-----x
RICHARD RICE, AS TRUSTEE OF THE :
RICHARD E. AND MELINDA RICE :
REVOCABLE FAMILY TRUST 5/9/90, and :
CHRISTIAN STANKEVITZ, Individually and : 21-cv-00036 (LJL)
On Behalf of All Others Similarly Situated, :
:
Plaintiff, : ORAL ARGUMENT REQUESTED
:
v. :
:
INTERCEPT PHARMACEUTICALS, INC., :
MARK PRUZANSKI, and SANDIP S. :
KAPADIA,
:
Defendants.

-----x
**DEFENDANTS' MEMORANDUM OF LAW IN SUPPORT OF THEIR
MOTION TO DISMISS PLAINTIFFS' FIRST AMENDED COMPLAINT**

James R. Carroll (*pro hac vice*)
Alisha Q. Nanda
Rene H. DuBois
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
500 Boylston Street
Boston, Massachusetts 02116
Telephone: (617) 573-4800

Scott D. Musoff
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Telephone: (212) 735-3000

*Attorneys for Defendants
Intercept Pharmaceuticals, Inc.,
Mark Pruzanski and Sandip S. Kapadia*

TABLE OF CONTENTS

TABLE OF AUTHORITIES	iii
PRELIMINARY STATEMENT	1
FACTUAL BACKGROUND.....	3
A. Intercept Developed OCA To Treat Two <i>Different</i> Progressive Liver Diseases Based On <i>Different</i> Therapeutic Targets	3
B. Intercept Successfully Submitted The First-Ever New Drug Application For Noncirrhotic NASH With Liver Fibrosis	4
C. The FDA Postponed The AdCom And Issued A Complete Response Letter	4
D. Serious Adverse Events Were Reported In Patients Taking Ocaliva For PBC, But Those Reports Did Not Show A Causal Connection.....	5
E. Intercept Disclosed A Potential Newly Identified Safety Signal Investigation For Ocaliva In PBC Patients With <i>Cirrhosis</i>	7
ARGUMENT	8
I. PLAINTIFFS FAIL TO ALLEGE FACTS SUPPORTING A STRONG INFERENCE OF SCIENTER	8
A. Plaintiffs Do Not Sufficiently Allege Motive To Commit Fraud	8
B. Plaintiffs Do Not Sufficiently Allege Conscious Misbehavior Or Recklessness.....	10
1. Defendants Had No Duty To Disclose The Alleged SAEs.....	10
2. Defendants Had No Duty To Disclose The NISS Earlier In Time	19
3. Plaintiffs’ “Additional Scienter” Allegations Are Insufficient	26
II. THE COMPLAINT SHOULD BE DISMISSED BECAUSE IT DOES NOT ALLEGE A MATERIAL MISSTATEMENT OR OMISSION	28
A. The Alleged Omissions About The SAEs And The NISS Are Not Actionable	29
B. The Challenged Misrepresentations Are Not Actionable As A Matter of Law.....	30

III.	PLAINTIFFS FAIL TO ADEQUATELY ALLEGE LOSS CAUSATION.....	34
IV.	COUNT II ALLEGING CONTROL PERSON LIABILITY SHOULD BE DISMISSED	35
	CONCLUSION.....	35

TABLE OF AUTHORITIES

<u>CASES</u>	<u>PAGE(S)</u>
<i>Acito v. IMCERA Group, Inc.</i> , 47 F.3d 47 (2d Cir. 1995).....	9, 10, 22, 23
<i>Altayyar v. Etsy, Inc.</i> , 242 F. Supp. 3d 161 (E.D.N.Y. 2017), <i>aff'd</i> , 731 F. App'x 35 (2d Cir. 2018).....	20, 26
<i>In re Amarin Corp. PLC Securities Litigation</i> , 689 F. App'x 124 (3d Cir. 2017)	31
<i>In re Aratana Therapeutics Inc. Securities Litigation</i> , 315 F. Supp. 3d 737 (S.D.N.Y. 2018).....	9
<i>In re Bank of America AIG Disclosure Securities Litigation</i> , 980 F. Supp. 2d 564 (S.D.N.Y. 2013), <i>aff'd</i> , 566 F. App'x 93 (2d Cir. 2014).....	29
<i>Basic Inc. v. Levinson</i> , 485 U.S. 224 (1988).....	24
<i>In re Bristol-Myers Squibb Securities Litigation</i> , 312 F. Supp. 2d 549 (S.D.N.Y. 2004).....	9
<i>Chapman v. Mueller Water Products, Inc.</i> , 466 F. Supp. 3d 382 (S.D.N.Y. 2020).....	32, 35
<i>Central States, Southeast and Southwest Areas Pension Fund v. Federal Home Loan Mortgage Corp.</i> , 543 F. App'x 72, 75 (2d Cir. 2013).....	35
<i>Chill v. General Electric Co.</i> , 101 F.3d 263 (2d Cir. 1996).....	22
<i>Chipman v. Aspenbio Pharma, Inc.</i> , No. 11-CV-00163-REB-KMT, 2012 WL 4069353 (D. Colo. Sept. 17, 2012)	26, 30
<i>City of Brockton Retirement System v. Avon Products, Inc.</i> , No. 11 CIV. 4665 (PGG), 2014 WL 4832321 (S.D.N.Y. Sept. 29, 2014)	8
<i>City of Edinburgh Council v. Pfizer, Inc.</i> , 754 F.3d 159 (3d Cir. 2014).....	24
<i>ECA, Local 134 IBEW Joint Pension Trust of Chicago v. JP Morgan Chase Co.</i> , 553 F.3d 187 (2d Cir. 2009).....	8
<i>In re Elan Corp. Securities Litigation</i> , 543 F. Supp. 2d 187 (S.D.N.Y. 2008).....	10, 16, 20

<i>Fort Worth Employers' Retirement Fund v. Biovail Corp.</i> , 615 F. Supp. 2d 218 (S.D.N.Y. 2009).....	31
<i>In re Gildan Activewear, Inc. Securities Litigation</i> , 636 F. Supp. 2d 261 (S.D.N.Y. 2009).....	9
<i>Glaser v. The9, Ltd.</i> , 772 F. Supp. 2d 573 (S.D.N.Y. 2011).....	9, 28
<i>Gregory v. ProNAi Therapeutics Inc.</i> , 297 F. Supp. 3d 372 (S.D.N.Y. 2018), <i>aff'd</i> , 757 F. App'x 35 (2d Cir. 2018).....	29
<i>Higginbotham v. Baxter International Inc.</i> , 495 F.3d 753 (7th Cir. 2007)	20
<i>Inter-Local Pension Fund GCC/IBT v. General Electric Co.</i> , 445 F. App'x 368 (2d Cir. 2011)	19
<i>Jackson v. Abernathy</i> , 960 F.3d 94 (2d Cir. 2020).....	18, 27
<i>Janbay v. Canadian Solar, Inc.</i> , No. 10-Civ-4430 (RWS), 2012 WL 1080306 (S.D.N.Y. Mar. 30, 2012)	35
<i>Kader v. Sarepta Therapeutics, Inc.</i> , 887 F.3d 48 (1st Cir. 2018).....	22
<i>Kalnit v. Eichler</i> , 264 F.3d 131 (2d Cir. 2001).....	8, 10, 22
<i>Kleinman v. Elan Corp., plc</i> , 706 F.3d 145 (2d Cir. 2013).....	3, 18, 24, 31, 33
<i>Koncelik v. Savient Pharms., Inc.</i> , 448 F. App'x 154 (2d Cir. 2012)	19
<i>Liu v. Intercept Pharmaceuticals, Inc.</i> , No. 17-cv-7371 (LAK), 2020 WL 1489831 (S.D.N.Y. Mar. 26, 2020), <i>appeal pending</i> , No. 20-3488 (2d Cir. filed Oct. 9, 2020).....	5, 13
<i>Liu v. Intercept Pharmaceuticals, Inc.</i> , No. 17-cv-7371 (LAK), 2020 WL 5441345 (S.D.N.Y. Sept. 9, 2020), <i>appeal pending</i> , No. 20-3488 (2d Cir. filed Oct. 9, 2020).....	5, 19
<i>Matrixx Initiatives, Inc. v. Siracusano</i> , 563 U.S. 27 (2011).....	2, 10, 11, 13, 15, 19, 29

<i>In re Meridia Products Liability Litigation,</i> 328 F. Supp. 2d 791 (N.D. Ohio 2004), <i>aff'd</i> , 447 F.3d 861 (6th Cir. 2006)	14
<i>New Jersey Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.,</i> 537 F.3d 35 (1st Cir. 2008).....	13, 16
<i>Nguyen v. New Link Genetics Corp.,</i> No. 16CV3545, 2019 WL 591556 (S.D.N.Y. Feb. 13, 2019)	18
<i>North Collier Fire Control and Rescue District Firefighter Pension Plan & Plymouth County Retirement Association v. MDC Partners, Inc.,</i> No. 15 Civ. 6034 (RJS), 2016 WL 5794774 (S.D.N.Y. Sept. 30, 2016).....	28
<i>Novak v. Kasaks,</i> 216 F.3d 300 (2d Cir. 2000).....	10
<i>In re Pfizer, Inc. Securities Litigation,</i> 538 F. Supp. 2d 621 (S.D.N.Y. 2008).....	30
<i>Philco Investments, Ltd. v. Martin,</i> No. C 10-02785 CRB, 2011 WL 4595247 (N.D. Cal. Oct. 4, 2011).....	19
<i>Plumbers & Steamfitters Local 773 Pension Fund v. Canadian Imperial Bank of Commerce,</i> 694 F. Supp. 2d 287 (S.D.N.Y. 2010).....	25
<i>In re Sanofi Securities Litigation,</i> 155 F. Supp. 3d 386 (S.D.N.Y. 2016).....	23, 34
<i>In re Sanofi Securities Litigation,</i> 87 F. Supp. 3d 510 (S.D.N.Y. 2015), <i>aff'd sub nom., Tongue v. Sanofi</i> , 816 F.3d 199 (2d Cir. 2016).....	31, 33
<i>Shemian v. Research In Motion Ltd.,</i> No. 11 CIV. 4068 RJS, 2013 WL 1285779 (S.D.N.Y. Mar. 29, 2013), <i>aff'd</i> , 570 F. App'x 32 (2d Cir. 2014).....	24, 27, 30
<i>Singh v. Cigna Corp.,</i> 277 F. Supp. 3d 291 (D. Conn. 2017), <i>aff'd</i> , 918 F.3d 57 (2d Cir. 2019)	34
<i>Singh v. Schikan,</i> 106 F. Supp. 3d 439 (S.D.N.Y. 2015).....	26
<i>Slayton v. American Express Co.,</i> 604 F.3d 758 (2d Cir. 2010).....	21
<i>South Cherry Street, LLC v. Hennessee Group LLC,</i> 573 F.3d 98 (2d Cir. 2009).....	22, 26

<i>Tellabs, Inc. v. Makor Issues & Rights, Ltd.,</i> 551 U.S. 308 (2007).....	8
<i>Tongue v. Sanofi,</i> 816 F.3d 199 (2d. Cir. 2016).....	18
<i>Tyler v. Liz Claiborne, Inc.,</i> 814 F. Supp. 2d 323 (S.D.N.Y. 2011).....	25
<i>White v. H&R Block, Inc.,</i> No. 02 CIV. 8965 (MBM), 2004 WL 1698628 (S.D.N.Y. July 28, 2004).....	26
<i>Yan v. ReWalk Robotics Ltd.,</i> 973 F.3d 22 (1st Cir. 2020).....	27
<i>Ziebron v. Metaldyne Corp.,</i> No. 09-10164, 2010 WL 11544989 (E.D. Mich. Sept. 28, 2010).....	26

<u>STATUTES AND REGULATIONS</u>	<u>PAGE(S)</u>
15 U.S.C. § 78u-4	8
21 U.S.C. § 355.....	18
21 C.F.R. § 201.57.....	17
21 C.F.R. § 314.80.....	6, 17
21 C.F.R. § 314.110.....	4
21 C.F.R. § 314.102.....	5

PRELIMINARY STATEMENT

Intercept Pharmaceuticals, Inc. (“Intercept”) is a biopharmaceutical company that develops and commercializes therapeutics to treat progressive non-viral liver diseases using its proprietary bile acid chemistry. Since 2016, Intercept’s FDA-approved drug Ocaliva® (obeticholic acid or “OCA”) has treated thousands of patients with primary biliary cholangitis (“PBC”—a rare but devastating progressive liver disease that primarily results from autoimmune destruction of the bile ducts that transport bile acids out of the liver. (FAC ¶¶ 4, 30.) As PBC progresses, it causes liver damage, cirrhosis, and ultimately liver failure, transplant or death. (FAC ¶¶ 30-31.) Intercept has also been developing OCA to treat a more common, but very *different* progressive liver disease, noncirrhotic non-alcoholic steatohepatitis (“noncirrhotic NASH”), which induces inflammation and liver damage, resulting in fibrosis. (FAC ¶¶ 37-39.)

In September 2019, the Food and Drug Administration (“FDA”) accepted Intercept’s submission of the first-ever new drug application (“NDA”) seeking accelerated approval for noncirrhotic NASH. In May 2020, the FDA requested additional data from Intercept and postponed an advisory committee meeting to permit time to review that data. Around this same time, the FDA separately informed Intercept’s pharmacovigilance team that it was investigating a “newly identified safety signal” (“NISS”) with Ocaliva. A NISS is a potential safety issue with a drug but it does not mean that there is evidence of a causal link between the drug and the safety issue. The NISS was largely identified through serious adverse event (“SAE”) reports submitted to the FDA showing that a subset of advanced PBC patients with cirrhosis had experienced certain liver-related SAEs. The FDA estimated that its NISS investigation would take up to a year to complete. On June 29, 2020, Intercept announced that the FDA had informed it that the noncirrhotic NASH NDA data was insufficient to support accelerated approval and recommended that additional efficacy and safety data from the ongoing Phase 3 trial be included

in any resubmission. Intercept continues to work with the FDA on the potential resubmission of the noncirrhotic NASH NDA.

Seizing on these FDA communications, Plaintiffs claim that from September 27, 2019 through October 8, 2020 (the alleged “Class Period”), Defendants knew but fraudulently failed to disclose that there were several liver-related SAEs in PBC patients taking Ocaliva that were not listed on the label that created a material risk to the approval of the noncirrhotic NASH NDA. Plaintiffs’ fraud-by-hindsight theory is critically flawed for at least the following reasons.

First, Plaintiffs’ theory ignores that securities laws do not require companies to disclose to investors the occurrence of SAEs that are reported to the FDA because the “mere existence of reports of adverse events . . . says nothing in and of itself about whether the drug is causing the adverse events.” *Matrixx Initiatives, Inc. v. Siracusano*, 563 U.S. 27, 44 (2011). Indeed, Plaintiffs ignore that the occurrence of certain liver-related SAEs in PBC patients is expected because PBC progressively damages the liver and many PBC patients suffer from liver-related comorbidities. Accordingly, the SAEs often do not provide sufficient information to assess whether Ocaliva or the patient’s underlying disease(s) caused the event. (*Infra* at Section I.B.1.)

Second, Plaintiffs’ claims hinge on their speculative allegation that the FDA’s NISS investigation in the subset of *PBC* patients with *cirrhosis* was tied to the FDA’s decision to deny the NDA for *noncirrhotic NASH*, an entirely different disease. But Plaintiffs fail to support that claim with any plausible or particularized factual allegations. Indeed, Plaintiffs offer no allegations supported by any witnesses (confidential or otherwise), any Intercept internal documents, any FDA communications or any other factual support. The public-record facts undermine Plaintiffs’ suggestion that the NISS investigation posed a material risk to the NASH NDA. (*Infra* at Section I.B.2.) Plaintiffs’ claims should be dismissed with prejudice.

FACTUAL BACKGROUND¹

A. Intercept Developed OCA To Treat Two *Different Progressive Liver Diseases Based On Different Therapeutic Targets*

Ocaliva has treated thousands of patients since its FDA approval in May 2016 and has accumulated over 14,000 patient years of exposure² as of November 2020. (FAC ¶ 32; Ex. 1 (Nov. 9, 2020 Call Tr.) at 7.) To combat PBC, Ocaliva targets the FXR receptor in the liver that regulates bile acid pathways, and seeks to reduce bile production and increase the flow of bile acids out of the liver. (FAC ¶¶ 29, 31.) Unlike PBC, which causes toxic bile build-up in the liver (called “cholestatic toxicity”), noncirrhotic NASH is a *non-cholestatic* liver disease caused by “excessive fat accumulation in the liver (steatosis) that induces chronic inflammation,” which can cause fibrosis and lead to “liver failure, cancer and death.” (FAC ¶ 38.) “[T]he metabolism and the on-target therapeutic benefits” of OCA in noncirrhotic NASH patients are very different than those in PBC patients. (Ex. 2 (Feb. 1, 2018 Call Tr.) at 10.) Although OCA targets the same FXR receptor in both diseases, OCA treats cholestatic toxicity in PBC patients, but not in noncirrhotic NASH patients, where the toxic bile does not build up (it flows freely). (*Id.*; FAC ¶ 29.) Put simply, PBC and NASH “are entirely different diseases that have different targets that are being addressed.” (Ex. 2 (Feb. 1, 2018 Call Tr.) at 10.)

¹ The Court may properly consider documents referenced or incorporated in, or integral to, the FAC, matters of public record and SEC filings. *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 152 (2d Cir. 2013). The foregoing documents are attached to the Declaration of Scott D. Musoff dated April 26, 2021, cited herein as “Ex. ____”.

² “Patient years” represents the estimated number of patients exposed to a drug multiplied by the length of exposure. For example, if 100 patients took Ocaliva with 50 of them exposed for 1 year and the other 50 exposed for 2 years, that would be the equivalent of 150 “patient years.” “Patient years” is used to calculate crude reporting rates of SAEs. (*See infra* at n.13.)

B. Intercept Successfully Submitted The First-Ever New Drug Application For Noncirrhotic NASH With Liver Fibrosis

On September 27, 2019, Intercept submitted its NDA seeking accelerated approval for noncirrhotic NASH based on positive interim-analysis results from a Phase 3 study (“REGENERATE”) showing that OCA met its primary endpoint of improving liver fibrosis with no worsening of NASH at an 18-month interval (the only drug to have done so). (FAC ¶¶ 37, 40, 52-54; Ex. 3 (Sept. 27, 2019 Press Release).) On November 25, 2019, the FDA accepted the NDA and granted it priority review (targeting a 6-month review). (FAC ¶ 56.) The FDA planned to hold an advisory committee meeting (“AdCom”), which is a routine event during the drug approval process, but no date was set and the timeline was subject to change. (*Id.*)

C. The FDA Postponed The AdCom And Issued A Complete Response Letter

The FDA initially scheduled the AdCom for April 22, 2020, but that meeting was postponed due to the COVID-19 pandemic. (FAC ¶¶ 56-57, 59.) On May 22, 2020, Intercept announced that the FDA postponed the AdCom meeting again, this time to accommodate the review of additional data that the FDA requested. (FAC ¶ 65; Ex. 4 (May 22, 2020 Press Release).) On this same day, Intercept’s stock price fell \$11.18 to close at \$80.51 per share, a decline of 12.19%. (FAC ¶ 116.) On June 29, 2020, Intercept disclosed that the FDA had issued a Complete Response Letter (“CRL”)³ for the noncirrhotic NASH NDA. (FAC ¶ 67; Ex. 5 (June 29, 2020 Press Release).) Intercept stated that “based on the data the FDA has reviewed to date, the Agency has determined that the predicted benefit of OCA based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks

³ The FDA sends a CRL if it will not approve the NDA in its present form, and requires an applicant to either resubmit the NDA addressing any deficiencies, withdraw the NDA, or request an opportunity for a hearing. 21 C.F.R. 314.110 (a), (b).

to support accelerated approval for the treatment of patients with liver fibrosis due to NASH.” (*Id.*) Intercept explained that the FDA “progressively increased the complexity of the histologic endpoints” for noncirrhotic NASH and that only OCA had so far met those endpoints. (Ex. 5 (June 29, 2020 Press Release) at 1.) The FDA told Intercept to “submit additional post-interim analysis efficacy and safety data from the ongoing REGENERATE study in support of potential accelerated approval and that the long-term outcomes phase of the study should continue.” (*Id.*) This same day, Intercept’s stock price fell \$30.79 to close at \$46.70 per share, a decline of 39.73%. (FAC ¶ 119.) Intercept has not withdrawn the NDA and continues to work with the FDA for potential resubmission and approval, including meeting with the FDA for the end-of-review conference (21 C.F.R. § 314.102(d)) and obtaining and analyzing additional data needed for resubmission. (Ex. 6 (Aug. 10, 2020 Press Release); Ex. 1 (Nov. 9, 2020 Call Tr.) at 4.)

D. Serious Adverse Events Were Reported In Patients Taking Ocaliva For PBC, But Those Reports Did Not Show A Causal Connection

Following Ocaliva’s approval for PBC in May 2016, Intercept and the FDA received reports of 19 cases of death and 11 cases of serious liver injury in 27 PBC patients who were incorrectly prescribed higher doses of Ocaliva than recommended on its label. (FAC ¶ 34.) In response, in September 2017, Intercept issued a letter to healthcare professionals, and the FDA issued a related drug safety communication, identifying the SAEs and reinforcing the dosing recommendations set forth in the Ocaliva label.⁴ (*Id.*) In February 2018, Intercept and the FDA revised the Ocaliva label with a “black box warning” stating that SAEs of liver failure and

⁴ Seizing on these events, a securities fraud class action much like this one was filed against largely the same Defendants here alleging that Intercept misled investors by failing to disclose those SAEs. Those claims were dismissed twice. *Liu v. Intercept Pharm., Inc.*, No. 17-cv-7371 (LAK), 2020 WL 1489831 (S.D.N.Y. Mar. 26, 2020) and 2020 WL 5441345 (S.D.N.Y. Sept. 9, 2020), *appeal pending*, No. 20-3488 (2d Cir. filed Oct. 9, 2020).

hepatic decompensation were reported in PBC patients who were misdosed and highlighting the correct dosage. (FAC ¶ 35; Ex. 7 (2018 Ocaliva Label).) The FDA did not make any conclusions about a causal link between the SAEs and Ocaliva and did not withdraw Ocaliva from the market or limit Intercept’s ability to market Ocaliva. (*See id.*)

Plaintiffs allege that following Ocaliva’s label change in February 2018, Defendants became aware of (but did not disclose) certain liver-related SAEs and “active liver toxicity signals” that “were not already cited on Ocaliva’s label” and that were “not known about and previously addressed by the FDA.” (FAC ¶¶ 42, 47.) As part of its post-marketing pharmacovigilance requirements, Intercept reports to the FDA solicited and unsolicited (or “spontaneous”⁵) SAEs that are reported to the company by healthcare providers or consumers that may be “associated with the use of a drug . . . whether or not considered drug related.” 21 C.F.R. § 314.80(a), (c) (emphasis added). Providers and patients may also directly report such SAEs to the FDA. The FDA aggregates these SAE reports on a quarterly basis and publishes them in its publicly-available adverse event reporting database called “FAERS.”⁶ The FDA recognizes that SAE reports published in FAERS have several significant limitations given the unverified nature of the voluntary reports: (i) the reports often contain incomplete information

⁵ “Spontaneous” SAEs are unsolicited, voluntary reports by a healthcare professional or consumer to a drug manufacturer or regulatory authority that are not from a controlled clinical study or any organized data collection scheme. 21 C.F.R. 314.80(f); see FDA, *Post-Approval Safety Data Management: Definitions and Standards for Expedited Reporting*, <https://www.fda.gov/files/drugs/published/E2D-Postapproval-Safety-Data-Management--Definitions-and-Standards-for-Expedited-Reporting.pdf>, at § 2.5.1.1.

⁶ The FAERS database is a “highly interactive web-based tool that allows for the querying of FAERS data in a user friendly fashion” and allows the public to view SAE reports for any FDA-approved drug going back to 1968. FDA, *Questions and Answers on FDA’s Adverse Event Reporting System (FAERS)*, <https://www.fda.gov/drugs/surveillance/questions-and-answers-fdas-adverse-event-reporting-system-faers>.

needed to properly evaluate an event; (ii) no causal connection is required to submit a report and no causal connection can be drawn from the report alone because the adverse event may be related to the underlying disease, a concomitant disease or another drug; (iii) duplicative reports are often submitted, and reporting rates may increase because of litigation, publicity, or black-box warnings; and (iv) the reports cannot be used to estimate incidence rates. (*Id.*)

E. Intercept Disclosed A Potential Newly Identified Safety Signal Investigation For Ocaliva In PBC Patients With Cirrhosis

In May 2020, the FDA notified Intercept that, “in the course of its routine safety surveillance” of the FAERS database, it had identified a NISS of “liver disorder” in certain PBC patients taking Ocaliva. (Ex. 8 (Aug. 10, 2020 10-Q) at 57, 64; FAC ¶ 63.) The NISS was classified as a “potential” risk (FAC ¶ 63), which is the *lowest* level of concern, and does not mean that the FDA had identified a causal relationship between Ocaliva and the “liver disorder”; it would take the FDA up to an entire year to investigate. (*See infra* at 21.) The FDA later informed Intercept that the NISS was focused on a subset of advanced PBC patients with *cirrhosis*. (FAC ¶¶ 48, 63.) Unlike patients with *noncirrhotic NASH*,⁷ PBC patients with cirrhosis are more likely to develop liver failure and serious liver-related SAEs at higher rates.⁸

On August 10, 2020, Intercept disclosed the FDA’s NISS investigation in its quarterly SEC filing in the risk factors section. (FAC ¶ 69; Ex. 8 (Aug. 10, 2020 10-Q) at 57, 64.) Even though Plaintiffs allege that the market for Intercept’s stock “promptly digested information regarding the Company from all publicly available sources,” they claim that the NISS

⁷ About only 10% of patients with NASH have or develop cirrhosis. (Ex. 9 (Dec. 16, 2019 Call Tr.) at 9.) For that reason, the FDA distinguishes between noncirrhotic and cirrhotic NASH in evaluating NDAs. (*See* Ex. 10 (Aug. 10, 2020 Call Tr.) at 15.)

⁸ See Nat’l Inst. of Diabetes and Digestive and Kidney Diseases, *Definition & Facts for Cirrhosis*, <https://www.niddk.nih.gov/health-information/liver-disease/cirrhosis/definition-facts>.

investigation disclosure was not noticed until October 8, 2020, when a news article was published discussing the NISS investigation. (*See* FAC ¶¶ 13, 71, 155; Ex. 11 (Oct. 8, 2020 STAT Article).) On this same day, Intercept’s stock price fell \$3.30 to close at \$37.69 per share, a decline of 8.05%. (FAC ¶ 122.) This securities fraud class action was filed shortly thereafter.

ARGUMENT

To state a claim under Section 10(b) of the Exchange Act and Rule 10b-5, Plaintiffs must plead: (1) a misrepresentation or omission of material fact; (2) scienter; (3) a connection between the misrepresentation or omission and the purchase or sale of a security; (4) reliance upon the misrepresentation or omission; and (5) loss causation and economic loss. *ECA, Loc. 134 IBEW Joint Pension Tr. of Chi. v. JP Morgan Chase Co.*, 553 F.3d 187, 197 (2d Cir. 2009).

I. PLAINTIFFS FAIL TO ALLEGE FACTS SUPPORTING A STRONG INFERENCE OF SCIENTER

Plaintiffs must allege particularized facts demonstrating a strong inference of scienter with respect to each act or omissions that is “cogent and at least as compelling as any opposing inference of nonfraudulent intent.” *Tellabs, Inc. v. Makor Issues & Rts., Ltd.*, 551 U.S. 308, 314 (2007); 15 U.S.C. § 78u-4(b)(2)(A). Scienter may be pleaded through particularized factual allegations of (1) “both motive and opportunity” for the defendant to commit fraud; or (2) “strong circumstantial evidence of conscious misbehavior or recklessness.” *City of Brockton Ret. Sys. v. Avon Prods., Inc.*, No. 11 Civ. 4665 (PGG), 2014 WL 4832321, at *18. Plaintiffs fail to meet either requirement.

A. Plaintiffs Do Not Sufficiently Allege Motive To Commit Fraud

To plead motive, Plaintiffs “must assert a concrete and personal benefit” to the Defendants. *Kalnit v. Eichler*, 264 F.3d 131, 139 (2d Cir. 2001). Plaintiffs’ only motive allegations are stock sales by a single Individual Defendant, Dr. Pruzanski (Intercept’s former

CEO and current board member), that were made two months into the 13-month Class Period. (FAC ¶¶ 138-140.) But Plaintiffs have not—and cannot—show that those stock trades were “unusual or suspicious” as the law requires. *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 270 (S.D.N.Y. 2009). Indeed, Plaintiff’s allegation that Dr. Pruzanski was motivated to conceal “the material risks impacting approval of the NASH NDA” because he was able to “sell a significant amount of his directly and indirectly owned shares” at inflated prices (FAC ¶¶ 138-139) is contradicted by the same publicly-available SEC Form 4 filings that Plaintiffs rely on. Those filings show that the alleged stock sales were *all* made “pursuant to a pre-existing Rule 10b5-1 trading plan.” (Ex. 12 (Form 4 Filings).) Courts consistently hold that such sales do not raise a strong inference of scienter. *Glaser v. The9, Ltd.*, 772 F. Supp. 2d 573, 592 (S.D.N.Y. 2011); *In re Aratana Therapeutics Inc. Sec. Litig.*, 315 F. Supp. 3d 737, 764 (S.D.N.Y. 2018).

Nor did Dr. Pruzanski “sell a significant amount” of his shares: the alleged stock sales represented only 8% of his total holdings, and his holdings actually *increased* during the alleged Class Period. (Ex. 12 Form 4 Filings (showing that Dr. Pruzanski started with 570,673 shares and ended with 575,517).) These circumstances also negate any inference of scienter. *Acito v. IMCERA Grp., Inc.*, 47 F.3d 47, 54 (2d Cir. 1995) (sale representing less than 11% of holdings did not support strong inference of scienter); *Glaser*, 772 F. Supp. 2d at 593 (increased holdings undercut inference of scienter); *In re Bristol-Myers Squibb Sec. Litig.*, 312 F. Supp. 2d 549, 561 (S.D.N.Y. 2004) (increased holdings are “wholly inconsistent with fraudulent intent”). Plaintiffs also do not (and cannot) allege insider trading by Mr. Kapadia, further negating an inference of

scienter. *Acito*, 47 F.3d at 54 (absence of other insider trades undercuts inference of fraud).⁹

B. Plaintiffs Do Not Sufficiently Allege Conscious Misbehavior Or Recklessness

Plaintiffs' allegations concerning circumstantial evidence of conscious misbehavior or recklessness also fail to raise a strong inference of scienter. (FAC ¶¶ 41-77; 124-144.) To state a claim under a recklessness theory based on a material omission, as Plaintiffs seek to do here, Plaintiffs must allege a “clear duty to disclose,” *Kalnit*, 264 F.3d at 144, and particularized facts supporting a strong inference of Defendants’ “conscious recklessness.” *Novak v. Kasaks*, 216 F.3d 300, 312 (2d Cir. 2000). Plaintiffs’ omission theories fail to meet this high standard.

1. Defendants Had No Duty To Disclose The Alleged SAEs

Plaintiffs’ primary theory of recklessness is that Defendants knew about but “failed to disclose that there were several serious adverse events from OCA in PBC patients that were not already cited on Ocaliva’s label” and that these SAEs presented a “material risk to approval of the NASH NDA” because they occurred in “patients taking the same drug.” (FAC ¶¶ 42, 81, 88, 90, 96.) But Defendants’ alleged recklessness cannot be inferred from this knowledge because Defendants had no duty to disclose the SAEs to investors.

In the context of post-marketing SAEs reported to the FDA, the securities laws do not require pharmaceutical companies to disclose SAEs to investors unless the reports “plausibly indicate[] a reliable causal link between [the use of a drug] and [the SAEs].” *Matrixx*, 563 U.S. at 45; see *In re Elan*, 543 F. Supp. 2d at 214 (dismissing claim because plaintiffs failed to “allege

⁹ Plaintiffs also point to Intercept’s pre-Class Period capital raise of \$450 million in May 2019. (FAC ¶¶ 52-53.) Plaintiffs cannot allege a fraudulent motive based on a capital raise that occurred well before any alleged misconduct took place. In any event, generalized allegations of motive to commit fraud in order to raise capital are insufficient to show scienter. *In re Elan Corp. Sec. Litig.*, 543 F. Supp. 2d 187, 215-16 (S.D.N.Y. 2008) (motive to conceal negative adverse events to complete \$1.15 billion senior notes offering did not support scienter).

facts that, if proven, would support an inference that a causal relationship between [the drug] and [the adverse events] was established but not disclosed during the Class Period”). In *Matrixx*, in response to allegations that a pharmaceutical company made misleading statements about a drug’s safety by failing to disclose certain SAEs, the Supreme Court reasoned that pharmaceutical companies need not disclose all reports of adverse events because the “fact that a user of a drug suffered an adverse event, standing alone, does not mean that the drug caused that event.” *Id.* at 44. Recognizing that thousands of adverse events are reported daily to the FDA from a variety of sources, the Supreme Court emphasized that “the mere existence of reports of adverse events—which says nothing in and of itself about whether the drug is causing the adverse events—will not satisfy [the materiality] standard. Something more is needed.” *Id.* That “something more” can come from “the source, content, and context of the reports.”¹⁰

Here, Plaintiffs point exclusively to the occurrence of certain liver-related SAEs in patients taking Ocaliva for PBC that were reported to the FDA and published in the FAERS database. In particular, Plaintiffs allege that, after the Ocaliva label was updated in February 2018 to emphasize the proper dosing in patients with advanced PBC, Defendants became aware of SAEs showing “active liver toxicity signals” in patients taking Ocaliva that were not already cited in Ocaliva’s label (or known to the FDA), and those SAEs therefore presented a material risk to Ocaliva’s commercial prospects and the NASH NDA. (FAC ¶¶ 41-48, 81.) Plaintiffs

¹⁰ In *Matrixx*, the Supreme Court found the following allegations—collectively—sufficient to show the “something more”: (i) “reports from three medical professionals and researchers about more than 10 patients” showing that patients experienced an adverse event after using the company’s drug; (ii) “during the class period, nine plaintiffs commenced four product liability lawsuits against [the company] alleging a causal link between [the drug] use and [SAE]”; (iii) allegations that the company knew that experts had “presented their findings about a causal link between [the drug] and [SAE] to a national medical conference”; and (iv) the company was aware of “studies that had demonstrated a biological causal link between [the drug] and [SAE].” 563 U.S. at 45-46. No such facts are even remotely alleged here.

premise their claim on a table that they cut and pasted from a news article published by www.evaluate.com listing certain SAEs that occurred in patients taking Ocaliva and certain associated statistical scores purportedly showing a potential safety signal (the “SAE Table”).¹¹ (FAC ¶ 43; *see* Ex. 14 (Oct. 13, 2020 Evaluate Article).) But as demonstrated below, the SAE Table contains wrong and incomplete information, and uses an unvalidated statistical metric that the FDA has said cannot be used to reliably assess causation between a drug and reported SAEs.

First, the SAE Table purports to list the “[m]ost frequently reported adverse events for Ocaliva in the hepatobiliary system organ class” but provides no context about the SAEs other than the type of adverse event experienced. (FAC ¶ 43.) For example, the SAE Table provides no information about the SAE reports from which the data is derived, including (i) whether the patient experienced any other adverse events or had any comorbidities, such as or other liver-related diseases, (ii) the outcome of the adverse event(s), (iii) use of concomitant drugs that may have contributed to the adverse event, (iv) the dosing regimen, (v) whether the patient stopped taking Ocaliva and the patient’s response, or (vi) any other information from the SAE reports.

(*See* FDA, *Adverse Event Reporting System (FAERS): Latest Quarterly Data Files*, <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-latest-quarterly-data-files>.) That missing information would be critical to any reliable causality assessment. As the FDA’s own guidance demonstrates, there are numerous other factors beyond the mere “frequency” of reported SAEs that should be analyzed in assessing whether a causal relationship between a drug and the SAE

¹¹ The data in the SAE Table was itself sourced from a private company called Advera Health Analytics that purportedly sells software that analyzes FAERS adverse event data. Advera Health Analytics, *Pharmacovigilance Signal Detection: The Complete Guide*, https://info.adverahealth.com/pharmacovigilance-signal-detection-the-complete-guide#next_generation_signal_detection_software (Ex. 13 (“Advera Guide”).)

may exist.¹² Yet Plaintiffs do not allege any facts whatsoever that address these factors or allege that any analysis of these factors was undertaken. The frequency of SAEs alone is not enough: “[s]omething more is needed.” *Matrixx*, 563 U.S. at 44.¹³

Second, the column in the SAE Table identifying the purported “risk odd ratio” (“ROR”) for each of the SAEs does not provide the “[s]omething more.” *Matrixx*, 56 U.S. at 44. ROR (also known as “Reporting Odds Ratio”) is one of several statistical methods used to identify potential *quantitative associations* between a drug and adverse events reported in the FAERS database.¹⁴ ROR measures the frequency of reporting of a particular adverse event for a particular drug compared to the same adverse event for all other drugs in the database; the resulting numerical score is then measured against a benchmark to determine if the adverse event was reported more than expected.¹⁵ (FAC ¶ 45; *see* Ex. 13 (Advera Guide) at 2.) Plaintiffs

¹² (Ex. 15 (Mar. 2005 FDA Guidance) at 6-7, 18 (factors include: “[t]emporal relationship of product use and the event,” “[b]iologic plausibility,” “[e]vidence of positive dechallenge or positive rechallenge,” and “concomitant medications that could contribute to the event”).)

¹³ Plaintiffs’ own allegations suggest that the SAEs were infrequent. The frequency (or crude reporting rate) of an SAE is calculated by dividing the number of SAEs by the amount of patient years. (Ex. 15 (Mar. 2005 FDA Guidance) at 11.) Plaintiffs allege there were a total of 169 cases of liver-related SAEs between May 2016 (when Ocaliva was approved) and October 2020 (when the article published the SAE Table). (FAC ¶ 43.) Over approximately that same period, Ocaliva accumulated 14,000 patient-years of exposure (*supra* at 3). This results in a reporting rate of ***just over 1%***. The reporting rate is ***0.65%*** if you consider just those SAEs that were allegedly “Not labelled.” Courts have found similar reporting rates to be insufficient. *Liu*, 2020 WL 1489831, at *8 (reporting rate of 0.9% did not demonstrate materiality under *Matrixx*); *N.J. Carpenters Pension & Annuity Funds v. Biogen IDEC Inc.*, 537 F.3d 35, 50 (1st Cir. 2008) (no inference of scienter where incidence rate was less than 1%).

¹⁴ Other standard statistical methods are the Proportional Reporting Ratio (PRR) (which is a method very similar to ROR) and the more advanced Empirical Bayesian Geometric Mean (EGBM). (Ex. 13 (Advera Guide) at 2; Ex. 16 (FDA Data Mining White Paper) at 2-3.)

¹⁵ ROR equals $(a/b)/(c/d)$ where a= the number of SAEs in question for the drug in question; b= the number of all other SAEs for the drug in question; c= the number of SAEs in question for all other drugs; d= the number of all other SAEs for all other drugs. (Ex. 13 (Advera Guide) at 2.)

allege that a “ROR score above 1 indicates a higher than expected reporting rate for a given adverse event” and “*while there is no widely accepted benchmark* regarding the level triggering a safety signal many in the industry assume that results above 2.0 *warrant attention.*” (FAC ¶ 45 (emphases added).)

With that backdrop, Plaintiffs allege that scores identified in the SAE Table “of more than 18 and almost 9 for liver failure and portal hypertension, respectively, are staggering” and therefore it is “absurd to think that the Company would not have been aware of these adverse events.” (FAC ¶ 46.) Plaintiffs’ allegations fundamentally misunderstand the value of these unvalidated ROR scores. Long-standing FDA guidance demonstrates that statistical methods such as RORs have significant limitations and cannot be used to prove causality:

- The methods are “*inherently exploratory or hypothesis generating*” and “*cannot be used in isolation to establish causality.*” (Ex. 15 (Mar. 2005 FDA Guidance) at 8-9; Ex. 16 (FDA Data Mining White Paper) at 11 (emphases added).)
- “When applying data mining to large databases (such as [F]AERS), *it is not unusual* for a product to have several product-event combinations with *scores above a specified threshold.*” (Ex. 15 (Mar. 2005 FDA Guidance) at 8-9 (emphases added).)
- Because frequentist methods such as ROR and PRR do not “adjust for small observed or expected number of reports of the product-event pair of interest,” the FDA uses “more advanced statistical methods” (*i.e.*, EBGM scores) that “*diminish the effect of spuriously high*” scores and reduce the number of “*false-positive safety signals.*” (Ex. 16 (FDA Data Mining White Paper) at 3 (emphases added).)
- The underlying FAERS data used to generate ROR scores contain reporting biases and significant limitations that prevent any reliable causality assessments. (*See supra*, Factual Background Section D.)

These circumstances doom Plaintiffs’ allegations that Intercept would have been alerted to a material safety risk with Ocaliva based on the allegedly “staggering” ROR scores.¹⁶ *At most*, the

¹⁶ Courts have similarly recognized that disproportionality statistical methods such as ROR and PRR cannot be used to establish causation. *See In re Meridia Prods. Liab. Litig.*, 328 F.

unvalidated ROR scores could be used to generate a hypothesis that might “warrant” further inquiry, but they come nowhere close to establishing the reliable evidence of a causal link required under *Matrixx*. In any event, Plaintiffs do not allege that Defendants were aware of any of those ROR scores *during* the alleged Class Period or that Defendants conducted any such similar ROR analysis themselves (nor were they required to).¹⁷ Indeed, the ROR scores on the SAE Table appear to have been calculated *after* the Class Period by a private software company that is not alleged to have any relationship to Intercept or to have been used by the FDA.¹⁸ (Ex. 14 (Oct. 13, 2020 Evaluate Article).)

Plaintiffs’ allegation that the liver-related SAEs were “problematic side effects for a drug that is meant to improve liver function” fares no better. (FAC ¶ 44.) Many of the alleged liver-related SAEs are confounding factors because they are events or diseases often found in patients with PBC or reported in association with PBC. Indeed, “[u]p to 10% of patients with features of PBC will have additional features of autoimmune hepatitis.”¹⁹ PBC is also a *progressive liver disease* that leads to worsening liver function over time, and therefore it is expected that some patients will experience liver-related adverse events. That is why the FDA and Intercept made clear in the revised February 2018 Ocaliva label that “there was insufficient information to rule out confounding factors . . . or the role of the patient’s underlying advanced disease” in post-

¹⁷ Supp. 2d 791, 808 (N.D. Ohio 2004) (holding that evidence of high proportional reporting rate was insufficient to demonstrate causation), *aff’d*, 447 F.3d 861 (6th Cir. 2006).

¹⁸ The FDA states that the “[u]se of data mining techniques is not a required part of signal identification or evaluation.” (Ex. 15 (Mar. 2005 FDA Guidance) at 9.)

¹⁹ The FDA acknowledges that there are various “commercially available software programs” that generate data mining scores, but it uses a software called “Empirica Signal” from a different private vendor, *not* Advera Health. (Ex. 16 (FDA Data Mining White Paper) at 10.)

¹⁹ See Andrea Gossard & Keith Lindor, Abstract to *Development of autoimmune hepatitis in primary biliary cirrhosis*, Liver Int’l, Oct. 2007, <https://pubmed.ncbi.nlm.nih.gov/17845536>.

marketing SAEs, as “it is not always possible to . . . establish a causal relationship to drug exposure, *particularly in PBC patients who have progressive liver disease.*” (Ex. 7 (2018 Ocaliva Label) at 6, 10 (emphasis added).) Plaintiffs (tellingly) omit that the very same news articles that they rely on recognized this precise point: “[o]ne caveat is that all of these issues could be related to the underlying disease, since PBC affects the liver. . . .” (Ex. 14 (Oct. 13, 2020 Evaluate Article) at 2; *see also* Ex. 11 (Oct. 8, 2020 STAT Article) at 2.) For these reasons alone, Plaintiffs’ ROR allegations are insufficient. *See Biogen IDEC Inc.*, 537 F.3d at 50 (reasoning that “[s]ome adverse events may be expected to occur randomly, especially with a drug designed to treat people that are already ill”); *In re Elan*, 543 F. Supp. 2d at 212 (allegations failed to explain whether adverse events were caused by drug or “the subject’s underlying condition, other medications being taken, or even chance”).

Third, Plaintiffs allege that Defendants became aware of five types of SAEs listed on the SAE Table that were not on Ocaliva’s label and therefore knew such events could “result in further restrictions on Ocaliva’s use and thus the market size for the drug.” (FAC ¶ 42.) Plaintiffs either deliberately misstate what is disclosed on Ocaliva’s label or failed to review Ocaliva’s publicly-available label before asserting these meritless allegations. The Ocaliva label shows that three of the five types SAEs listed as “Not labelled” *are in fact* disclosed right on the label. “Hepatic failure” (which includes acute and chronic liver failure) is listed on the Ocaliva label in multiple places:

In the boxed warning on the very first page . . .

In postmarketing reports, hepatic decompensation and failure, in some cases fatal, have been reported in patients with primary biliary cholangitis (PBC) with decompensated cirrhosis or Child-Pugh Class B or C hepatic impairment when OCALIVA was dosed more frequently than recommended. (5.1)

and in the Adverse Reactions section . . .

Hepatobiliary Disorders: liver failure, new onset cirrhosis, increased direct and total bilirubin, new or worsening of jaundice, ascites, worsening hepatic encephalopathy [*see Warnings and Precautions (5.1)*].

(Ex. 7 (2018 Ocaliva Label) at 1, 3, 6, 10.) Likewise, “portal hypertension” was listed as “Not labelled” on the SAE Table (FAC ¶ 43) *when in fact it was* on the Ocaliva label:

In PBC patients who received OCALIVA 25 mg once daily (2.5 times the highest recommended dosage) or 50 mg once daily (5 times the highest recommended dosage), a dose-dependent increase in the incidence of liver-related adverse reactions, including elevations in liver biochemical tests, ascites, jaundice, portal hypertension, and primary biliary cholangitis flare, was reported. Serious liver-related

(*Id.* at 13.) The fact that the other two “Not labelled” SAEs (hepatorenal syndrome²⁰ and autoimmune hepatitis) were not explicitly listed on the Ocaliva label does not support Plaintiffs’ claim, because Plaintiffs’ allegations ignore how adverse event reporting and drug labeling works. Although the FDA requires companies to report unexpected SAEs that are not listed in the current labeling without regard to causality, *see* 21 C.F.R. § 314.80(a), (*l*), the “[d]ecision[] about whether to include an adverse event from spontaneous reports in labeling” is a “*matter of judgment*” and typically based on numerous factors, including the “strength of causal relationship to the drug.” (Ex. 17 (Jan. 2006 FDA Guidance) at 8.) As the FDA recognizes, “[l]engthy lists of adverse events unlikely to have been caused by the drug are of little or no value to prescribers, and are therefore inappropriate for inclusion in labeling.” (*Id.* at 5.) For that reason, a drug label is required to list “only those adverse events for which there is *some basis to believe there is a causal relationship between the drug and the occurrence of the adverse event.*” 21 C.F.R. § 201.57(c)(7) (emphasis added); *see also id.* § 201.57(c)(6)(i).

Plaintiffs’ own allegations support the inference that Defendants had no basis to believe that there was a causal relationship between Ocaliva and the two “Not labelled” SAEs. For example, using Plaintiffs’ ROR metric, the six cases of “autoimmune hepatitis” resulted in a

²⁰ Hepatorenal syndrome is also a typical clinical sign of hepatic decompensation, which, as shown above, is also listed on the Ocaliva label. *See* Dina Mansour & Stuart McPherson, *Management of decompensated cirrhosis*, Clinical Med., Apr. 2018, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6334027/>.

score of 1.83, below the threshold of 2 that would allegedly “warrant attention.” (FAC ¶ 45.) Of the six cases of “hepatorenal syndrome” that allegedly resulted in a ROR score above 2, half of them were reported to the FDA in 2017, well before the FDA revised Ocaliva’s label in February 2018.²¹ (FAC ¶ 47.) These allegations undermine Plaintiffs’ conclusory claim that the unlabeled SAEs were “not previously addressed or not known about” and “could result in further restrictions on Ocaliva’s use and thus the market size for the drug.” (FAC ¶ 42.) To the extent that Plaintiffs disagree with Intercept’s business judgment in making complex pharmacoepidemiologic assessments about adverse event data, that is not securities fraud and has not in any event been alleged with particularity. *Tongue v. Sanofi*, 816 F.3d 199, 214 (2d. Cir. 2016) (affirming dismissal of securities claims and holding that dispute about the proper interpretation of data is not securities fraud); *Kleinman*, 706 F.3d at 154 (same); *Nguyen v. New Link Genetics Corp.*, No. 16CV3545, 2019 WL 591556, at *6 (S.D.N.Y. Feb. 13, 2019) (same).

Fourth, Plaintiffs’ conclusory allegations that Defendants were aware of the reported SAEs before the alleged Class Period because they learned of them “in real-time” also fail. (FAC ¶¶ 42, 47 & n.14.)²² “Allegations of access generally to reports, an internal analysis, or to a database are not particularized allegations sufficient to meet the PSLRA and Rule 9(b)’s

²¹ To see a listing of those cases, visit <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/fda-adverse-event-reporting-system-faers-public-dashboard> (access FAERS Public Dashboard; search “Ocaliva” by product; search “hepatorenal syndrome” as a reaction; review “Listing of Cases”; and review “Initial FDA Received Date”).

²² Plaintiffs’ allegations are also contradictory, as they admit that “it is unclear exactly when the Company would have learned about these serious adverse events” (FAC ¶ 47 n.14.) Nor did Intercept learn of the reports in “real time” through *daily* monitoring of the FAERS database because the SAEs are published on a quarterly basis. 21 U.S.C. § 355(k)(5). Plaintiffs’ attempt to charge Defendants with other employees’ purported knowledge about the SAEs is also unavailing because Plaintiffs cannot “separately allege misstatements by some individuals and knowledge belonging to some others where, [as here], there is no strong inference that, in fact, there was a connection between the two.” *Jackson v. Abernathy*, 960 F.3d 94, 99 (2d Cir. 2020).

exacting pleading standard.” *Liu*, 2020 WL 5441345, at *7; *see also Inter-Loc. Pension Fund GCC/IBT v. Gen. Elec. Co.*, 445 F. App’x 368, 370 (2d Cir. 2011) (allegations of access to “real-time” data insufficient where there were no facts alleged “indicating that the content of the reports or data” was inconsistent with the Class Period statements). As the Honorable Lewis A. Kaplan recently held in dismissing similar allegations about purported access to SAEs in the FAERS database, “the fact that the reported adverse events were available on the FDA’s public database” does not demonstrate scienter; the “public availability of the SAE reports undermines an inference of scienter.” *Liu*, 2020 WL 5441345, at *7 & n.57; *see also Philco Invs., Ltd. v. Martin*, No. C 10-02785 CRB, 2011 WL 4595247, at *6 (N.D. Cal. Oct. 4, 2011) (publicly-available FAERS data undercut inference that drug company acted with scienter in concealing adverse events).

When viewed either individually or collectively, Plaintiffs fail to allege plausible and particularized allegations that Defendants had any evidence of a “reliable causal link” between Ocaliva and the SAEs during the alleged Class Period. *Matrixx*, 563 U.S. at 45. Plaintiffs therefore fail to “raise an inference—‘cogent and at least as compelling as any opposing inference of nonfraudulent intent’—that [D]efendants recklessly or intentionally disregarded the risk that a causal connection might exist between [the use of Ocaliva] and [the alleged SAEs].” *Koncelik v. Savient Pharms., Inc.*, 448 F. App’x 154, 155 (2d Cir. 2012) (affirming dismissal and finding no scienter based on alleged failure to disclose SAEs).

2. Defendants Had No Duty To Disclose The NISS Earlier In Time

Plaintiffs’ second theory of recklessness is premised on Defendants’ alleged failure to disclose that, on an unspecified date in May 2020, the “FDA had informed the Company that the agency had identified the NISS with Ocaliva related to liver disorder and was going to investigate the risk, that this investigation created a substantial, undisclosed risk to Intercept’s

future revenue from Ocaliva sales to PBC patients and business, and that the serious adverse events that led to this investigation and the investigation itself were material risks to approval of the NASH NDA.” (FAC ¶¶ 64, 102, 104, 108, 112.)

Yet Plaintiffs admit that Defendants *disclosed* the NISS investigation on August 10, 2020. (FAC ¶¶ 64, 69; Ex. 8 (Aug. 10, 2020 10-Q) at 57, 64.) Defendants could not have acted recklessly in failing to disclose information that was in fact disclosed. *Altayyar v. Etsy, Inc.*, 242 F. Supp. 3d 161, 180 (E.D.N.Y. 2017) (“[D]efendants cannot be held liable for failing to disclose something that they disclosed.”), *aff’d*, 731 F. App’x 35 (2d Cir. 2018). Faced with this undisputed disclosure, Plaintiffs instead allege that Defendants should have disclosed the NISS investigation “promptly” (*i.e.*, sometime in May 2020) because the NISS investigation presented a material risk to: (i) Ocaliva’s commercial prospects for PBC and (ii) the pending NASH NDA. (FAC ¶¶ 64-70.) Plaintiffs’ allegations fail on both scores.

First, Defendants had no duty to disclose the NISS investigation “promptly” because courts recognize that companies “are permitted a reasonable amount of time to evaluate potentially negative information and to consider appropriate responses before a duty to disclose arises.” *In re Elan*, 543 F. Supp. 2d at 217; *Higginbotham v. Baxter Int’l Inc.*, 495 F.3d 753, 761 (7th Cir. 2007) (“Taking the time necessary to get things right is both proper and lawful. Managers cannot tell lies but are entitled to investigate for a reasonable time, until they have a full story to reveal.”). In *In re Elan Corp.*, the court held that a pharmaceutical company did not act with scienter by waiting to disclose adverse events because the “more reasonable inference is that Defendants used this time to investigate, to gather more information, and to confer with . . . the FDA before taking any action.” 543 F. Supp. 2d at 217.

So too here: Defendants learned of the NISS investigation in May 2020 and disclosed it

to the market in Intercept’s *very next quarterly filing* with the SEC on August 10, 2020. (FAC ¶ 69.) In the interim, the Company was in an ongoing dialogue with the FDA regarding the details, nature, and scope of the NISS investigation. (FAC ¶ 74.) During this back and forth with the FDA, Defendants learned that (i) the FDA identified the NISS during its routine safety monitoring, (ii) it was based largely on the SAEs reported in the FAERS database, (iii) it was initially characterized broadly as a signal of “liver disorder,” and (iv) the FDA had classified the NISS under its *lowest* category of concern, a “*potential* risk.” (Ex. 1 (Nov. 9, 2020 Call Tr.) at 6; Ex. 18 (Dec. 1, 2020 Conference Tr.) at 2-3.) Under the FDA’s guidance, a “*potential* risk” classification means that an “association has not been confirmed” between the drug and the event, and that the FDA would have an entire year to investigate. (Ex. 19 (FDA MAPP 4121.3) at 8-9, 15.)²³ The identification of a NISS also “does not mean that [the] FDA ha[d] concluded that the drug has the listed risk” or “identified a causal relationship between the drug and the listed risk” or that it would or would not take any regulatory action.²⁴ The FDA also informed Defendants that the NISS was focused on a subset of PBC patients who had developed cirrhosis. (FAC ¶ 63; Ex. 20 (Feb. 25, 2021 Call Tr.) at 5.) Based on these circumstances, a more compelling and cogent nonculpable inference is that Defendants were prudently seeking to “inform themselves and the public of the risks” of the NISS investigation before disclosing it to the market. *Slayton v. Am. Express Co.*, 604 F.3d 758, 777 (2d Cir. 2010). No inference of recklessness can

²³ In contrast, an “important potential risk” classification means that there was *evidence* of a safety risk and that the investigation would occur within 6 months; an “emergency” classification means that a risk has resulted in fatalities and “prompt” action is required. (*Id.* at 8-9, 14.)

²⁴ See FDA, *Potential Signals of Serious Risks/New Safety Information Identified from the FDA Adverse Event Reporting System (FAERS)*, <https://www.fda.gov/drugs/questions-and-answers-fdas-adverse-event-reporting-system-faers/potential-signals-serious-risksnew-safety-information-identified-fda-adverse-event-reporting-system>.

therefore be inferred from Defendants' decision not to disclose the NISS investigation the moment they learned of it. *See Acito*, 47 F.3d at 53 (finding absence of scienter where corporation waited a month before disclosing adverse FDA action).

Ignoring these circumstances, Plaintiffs ask this Court to draw an inference of fraud based on their entirely speculative allegation that Defendants were "possibly" seeking to conceal the NISS investigation to protect Intercept's stock price and its "reputation and credibility in the marketplace." (FAC ¶ 68). But a "plaintiff cannot base securities fraud claims on speculation and conclusory allegations." *Kalnit*, 264 F.3d at 142. Plaintiffs' conclusory allegations are in any event precisely the type of generalized allegations that can be attributed to any company and are therefore insufficient to plead a strong inference of scienter. *Chill v. Gen. Elec. Co.*, 101 F.3d 263, 267 (2d Cir. 1996) ("If scienter could be pleaded on that basis alone, virtually every company in the United States that experiences a downturn in stock price could be forced to defend securities fraud actions."); *S. Cherry St., LLC v. Hennessee Grp. LLC*, 573 F.3d 98, 109 (2d Cir. 2009) ("[D]esire to maintain a high credit rating for the corporation or otherwise sustain the appearance of corporate profitability" does not show a strong inference of fraudulent intent).

In February 2021, after the FDA's nearly year-long NISS investigation, the FDA communicated that Ocaliva's label should be modified with respect to the subset of PBC patients who developed cirrhosis. (FAC ¶ 77.) But that *post-Class Period* decision by the FDA cannot serve as the "scaffolding for any reasonable inference that the FDA had communicated anything to [Defendants]" during the earlier relevant period that would have required Defendants to disclose the NISS investigation earlier in time. *Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 58 (1st Cir. 2018) (affirming dismissal of securities claim). Plaintiffs' allegations boil down to a claim that Defendants were somehow reckless for failing to predict that the nearly year-long

NISS investigation would result in a change in Ocaliva’s label. Defendants’ “lack of clairvoyance simply does not constitute securities fraud.” *Acito*, 47 F.3d at 53.

Second, Plaintiffs allege that the NISS investigation posed a “material risk to the pending NASH NDA” and thus Defendants were reckless in failing to disclose it on (i) May 22, 2020 when discussing the FDA’s decision to postpone the AdCom, and (ii) June 29, 2020 when discussing the FDA’s CRL for the noncirrhotic NASH NDA. (FAC ¶¶ 64-67.) Plaintiffs are wrong. “The critical consideration” for determining whether a corporation must disclose alleged omissions is whether the alleged omissions “are *sufficiently connected* to defendants’ existing disclosures to make those public statements misleading.” *In re Sanofi Sec. Litig.*, 155 F. Supp. 3d 386, 403 (S.D.N.Y. 2016) (emphasis added). Far from showing the requisite sufficient connection, Plaintiffs’ allegations compare apples to oranges: nowhere do they cite any particularized facts supporting an inference that the FDA’s decisions on the *noncirrhotic NASH* NDA were tied to its separate NISS investigation in a subset of patients with a different disease, PBC with advanced *cirrhosis*. For example, the May 22, 2020 press release indicated that the FDA had postponed the advisory committee meeting so that it could review additional data pertaining to the *noncirrhotic NASH* NDA. (Ex. 4 (May 22, 2020 Press Release).) As Intercept later disclosed, the additional data related to a “comprehensive liver health assessment” in the *noncirrhotic NASH* population. (Ex. 21 (June 29, 2020 Call Tr.) at 12-13, 15.) Plaintiffs do not allege any facts showing that the health assessment concerned *PBC* patients with *cirrhosis*.

The June 29, 2020 press release disclosing the CRL stated that the FDA had determined that the *noncirrhotic NASH* NDA was insufficient to support accelerated approval because the “predicted benefit of [Ocaliva] based on a surrogate histopathologic endpoint remains uncertain and does not sufficiently outweigh the potential risks.” (FAC ¶ 67.) Plaintiffs allege that,

because the CRL mentioned Ocaliva’s “potential risks,” Defendants were reckless in not disclosing the NISS investigation that involved the “same drug.” (*Id.*) Not so. Just because a pharmaceutical company speaks about the development of its drug in a particular disease, it does not mean that the company has a duty to disclose “any and all material information” about that drug’s use in a *different* disease affecting a *different* therapeutic target “that may be relevant or of interest to a reasonable investor.” *Kleinman*, 706 F.3d at 152, 154-55 (affirming dismissal of securities fraud claim against pharmaceutical company and finding no duty to disclose negative data because nothing in the company’s press release suggested that such data was positive); *City of Edinburgh Council v. Pfizer, Inc.*, 754 F.3d 159, 174 (3d Cir. 2014) (finding no duty to disclose negative efficacy and safety data from clinical trial results because the company did not place the strength or nature of the results “in play”). The relevant question is “whether such information was necessary in light of the context, manner of presentation, and language of the statements at issue so that what was revealed would not be so incomplete as to mislead.”

Shemian v. Rsch. In Motion Ltd., No. 11 CIV. 4068 RJS, 2013 WL 1285779, at *20 (S.D.N.Y. Mar. 29, 2013) (internal quotation marks omitted), *aff’d*, 570 F. App’x 32 (2d Cir. 2014). The context of the June 29, 2020 press release was clear: Intercept disclosed its disappointment and disagreement with the FDA’s determination that Ocaliva did not support accelerated approval for patients suffering from *noncirrhotic NASH* and expressed its hope to work with the FDA to resubmit the NDA in the future. (Ex. 5 (June 29, 2020 Press Release).) The press release had nothing to do with PBC patients and did not make any affirmative representations about the benefits or safety of Ocaliva in PBC patients with cirrhosis. No reasonable investor would therefore have viewed the pending NISS investigation “as having significantly altered the ‘total mix’ of information made available.” *Basic Inc. v. Levinson*, 485 U.S. 224, 231-32 (1988).

Without any plausible or particularized allegations connecting the NISS investigation to the FDA’s adverse decision on the noncirrhotic NASH NDA, Plaintiffs resort to relying on news articles published *after* the alleged Class Period that speculation about such a connection. (See FAC ¶ 71 (“Did the FDA’s liver safety evaluation of Ocaliva, which began in May, contribute to the agency’s decision in June to reject the NASH application?”) and FAC ¶ 72 (“Whatever the reason for Intercept not mentioning the FDA review until last week, the fact this started in May fits chronologically with the NASH adcom postponement. Investors will now want to know whether the new toxicity signals were behind the June CRL . . .”).) Plaintiffs cannot plead scienter through speculative news articles. *Plumbers & Steamfitters Loc. 773 Pension Fund v. Canadian Imperial Bank of Com.*, 694 F. Supp. 2d 287, 300 (S.D.N.Y. 2010) (finding no scienter where media reports provided only speculation because “[a]lthough a plaintiff may use [news articles] in pleadings, ‘the news articles cited still must indicate particularized facts about a defendant’s conduct’”); *Tyler v. Liz Claiborne, Inc.*, 814 F. Supp. 2d 323, 336 (S.D.N.Y. 2011) (reasoning that “‘generalized . . . speculation’ in the media is insufficient”). Plaintiffs’ reliance on such overt media speculation only illustrates the weakness of their allegations.

Third, in an attempt to evade the undisputed fact that the NISS investigation was disclosed, Plaintiffs claim that Defendants attempted to “bury” that disclosure by placing the language in the “middle of boilerplate paragraphs deep in the quarterly report” and not addressing it in the “Company’s press release announcing its quarterly results or the corresponding earnings call.” (FAC ¶¶ 68-70.) That is nonsense. Intercept disclosed the NISS investigation precisely where a reasonable investor (and the SEC) would expect to find such disclosure, *i.e.*, under two separate *risk factor* sections discussing specific substantive risks related to potential “undesirable side effects” in patients taking Ocaliva and potential “safety and

labeling changes required by the FDA.” (Ex. 8 (Aug. 10, 2020 10-Q) at 56-57, 63-64.)

The placement of these specific risk factors about Ocaliva in the middle of the 10-Q does not render them “buried.” Courts recognize that not “every fact cannot be contained in the beginning” of an SEC filing. *Ziebron v. Metaldyne Corp.*, No. 09-10164, 2010 WL 11544989, at *3 (E.D. Mich. Sept. 28, 2010) (dismissing 10b-5 claim; disclosure near the end of an SEC filing was not “buried”); *Chipman v. Aspenbio Pharma, Inc.*, No. 11-CV-00163-REB-KMT, 2012 WL 4069353, at *6 (D. Colo. Sept. 17, 2012) (“disclosure is not ‘buried’ simply because it is . . . situated in the middle of a multi-page document”); *Singh v. Schikan*, 106 F. Supp. 3d 439, 448 (S.D.N.Y. 2015) (disclosure was not buried because it was “set out logically under appropriate headings, alongside related information”). Because Defendants adequately disclosed the NISS investigation in Intercept’s 10-Q, they had no duty to further speak about it in later communications discussing Intercept’s quarterly results.²⁵ *Etsy, Inc.*, 242 F. Supp. 3d at 180.

3. Plaintiffs’ “Additional Scienter” Allegations Are Insufficient

Plaintiffs’ “Additional Scienter” allegations (FAC ¶¶ 127-144) add nothing.

“Core Operations” Allegations. Plaintiffs allege that “Ocaliva was crucial to the

²⁵ Plaintiffs’ claim that Defendants’ “burying was successful because no one, including analysts, noticed the comment” until months later (FAC ¶¶ 70-71) is implausible and defies common sense and industry customs. Analysts routinely compare SEC filings using redlining software to quickly learn of changes in a company’s risk disclosures. This Court should not credit Plaintiffs’ conclusory allegations to the contrary. *S. Cherry St.*, 573 F.3d at 110 (“Determining whether a complaint states a plausible claim for relief . . . requires the reviewing court to draw on its judicial experience and common sense.”). In any event, Plaintiffs’ allegation is directly contradicted by their “fraud-on-the-market” presumption allegations that “the market for Intercept securities *promptly digested information regarding the Company from all publicly available sources* and impounded such information into the price of Intercept’s securities.” (*Id.* ¶ 155 (emphasis added).) “Plaintiffs cannot use this presumption to argue that the market price reflected [D]efendants’ purported misstatements but not the true statements contained in [Intercept’s] SEC filings.” *White v. H&R Block, Inc.*, No. 02 CIV. 8965 (MBM), 2004 WL 1698628, at *13 (S.D.N.Y. July 28, 2004).

Company’s success” and its “sole drug candidate” and that the use of OCA in noncirrhotic NASH was an important commercial opportunity, and thus the Individual Defendants *must have known* about the SAEs and the risk they presented to OCA and approval of the NASH NDA. (FAC ¶¶ 127-129.) Courts in this Circuit routinely reject “core operations” allegations, standing alone, as insufficient to support a strong inference of scienter. *Jackson*, 960 F.3d at 99 (finding “naked assertion” that product was a “key product” and of “such core importance” to company insufficient to allege scienter). Because Plaintiffs’ other scienter allegations are deficient, their core operations allegations do not add anything to the scienter calculus. *Shemian*, 2013 WL 1285779, at *18 (rejecting “core operations” inference where remaining scienter allegations were insufficient).

FDA “Back and Forth” Allegations. Plaintiffs allege that the Individual Defendants’ “exhaustive preparation” for the AdCom in connection with the noncirrhotic NASH NDA and their “constant stream of interactions” and “self-proclaimed dialogue” with the FDA raises an inference that they knew about the safety risks with Ocaliva and the NISS investigation and the “material risk to the FDA approval of the NASH NDA.” (FAC ¶¶ 130-137.) This is more of the same: Plaintiffs allege zero facts that would permit an inference that the FDA’s NISS investigation was tied to its decisions on the noncirrhotic NASH NDA or that the additional data requests had anything to do with the NISS. The Individual Defendants’ alleged “back and forth” with the FDA is what one would expect responsible management to do when seeking to get a drug approved. Those “back-and forth” FDA conversations, without more, are “insufficient to support a strong inference of scienter.” *Yan v. ReWalk Robotics Ltd.*, 973 F.3d 22, 41 (1st Cir. 2020) (allegations that executives “had knowledge of the back-and-forth with the FDA” and importance of obtaining regulatory approval did not support inference of scienter where no facts

alleged showing that information learned was at odds with public statements).

Resignation Allegations. Plaintiffs ask this Court to draw the “most logical inference” of fraud from the *post-Class Period* resignations of Dr. Pruzanski, Mr. Kapadia, and another non-defendant executive Jason Campagna. (FAC ¶¶ 141-144.) The mere resignation of officers does not support a strong inference of scienter. *Glaser*, 772 F. Supp. 2d at 598. Plaintiffs do not even come close to alleging anything “highly unusual and suspicious” about the resignations and the public-record facts discredit their allegations: (i) Dr. Pruzanski retired as CEO after nearly 20 years at the helm and *continues to serve on Intercept’s board and as a consultant to the company*; and (ii) Mr. Kapadia and Dr. Campagna (who also currently serves as a consultant to the company) left Intercept to become executive officers of other biopharma companies. (Ex. 22 (Dec. 10, 2020 Press Release); Ex. 23 (Feb. 22, 2021 Form 8-K); Ex. 24 (Mar. 10, 2021 Press Release).) The FAC contains no allegations supporting an inference that these post-Class Period resignations were tied to the alleged fraud that is at least as compelling as an inference that the executives resigned in the normal course. *N. Collier Fire Control and Rescue Dist. Firefighter Pension Plan & Plymouth Cnty. Ret. Ass’n v. MDC Partners, Inc.*, No. 15 Civ. 6034 (RJS), 2016 WL 5794774, at *21 (S.D.N.Y. Sept. 30, 2016) (resignations did not support scienter where they occurred “several months after the Class Period ended” and executives could have left for one of the “myriad other reasons an executive might resign”).

II. THE COMPLAINT SHOULD BE DISMISSED BECAUSE IT DOES NOT ALLEGE A MATERIAL MISSTATEMENT OR OMISSION

Plaintiffs challenge various statements made during the Class Period as misleading because Defendants allegedly failed to disclose the SAEs and the NISS investigation. (FAC ¶¶ 80-112.) None of the alleged omissions or misstatements are actionable as a matter of law.

A. The Alleged Omissions About The SAEs And The NISS Are Not Actionable

For substantially the same reasons that Plaintiffs' unparticularized allegations about the SAEs and the NISS investigation fail to support a strong inference of scienter, Plaintiffs have also not pled an actionable omission based on those allegations. (*See supra* at 10-26.)

First, Plaintiffs do not allege any particularized facts showing that Defendants had evidence of a "reliable causal link" between Ocaliva and the SAEs and thus the allegedly omitted SAEs were immaterial as a matter of law. *Matrixx*, 563 U.S. at 45.

Second, the allegedly omitted SAEs were not materially misleading for the independent reason that they were disclosed to the FDA and readily accessible to the public on the FDA's website. Where, as here, "allegedly undisclosed material information is in fact readily accessible in the public domain . . . a defendant may not be held liable for failing to disclose this information." *In re Bank of Am. AIG Disclosure Sec. Litig.*, 980 F. Supp. 2d 564, 576 (S.D.N.Y. 2013), *aff'd*, 566 F. App'x 93 (2d Cir. 2014); *Gregory v. ProNAi Therapeutics Inc.*, 297 F. Supp. 3d 372, 410-11 (S.D.N.Y. 2018), *aff'd*, 757 F. App'x 35 (2d Cir. 2018) (rejecting allegations that company's statements about its drug were misleading by failing to disclose clinical trial amendments because the amendments were disclosed on the government's website (clinicaltrials.gov) and "[w]here cognizable materials reveal a public disclosure, the Court is not required to blink reality and accept as a true a plaintiff's claim of non-disclosure").

Here, all of the SAEs identified in Plaintiffs' SAE Table were publicly disclosed in the FDA's publicly-available FAERS database on the FDA's website. (*See supra* at n.6, n.21.) A simple search for Ocaliva on the FAERS database would have revealed precisely what Plaintiffs allege Defendants hid from the public: that PBC patients taking Ocaliva had experienced certain liver-related SAEs (most of which were listed as a type of SAE on Ocaliva's label). The search would have shown, among other things, the type of adverse event, when the SAE was reported to

the FDA, the seriousness of the event, and the patient's outcome. Because every one of the allegedly concealed SAEs was in the public domain during the Class Period, Defendants cannot be liable for allegedly omitting them. *In re Pfizer, Inc. Sec. Litig.*, 538 F. Supp. 2d 621, 633 (S.D.N.Y. 2008) (dismissing securities fraud claim and finding that “allegedly omitted information [about a company’s drug’s efficacy]” was “available publicly during the class period”); *Chipman*, 2012 WL 4069353, at *6 (dismissing securities fraud claim where allegedly concealed information was accessible from the U.S. Patent and Trademark Office).

Third, for the reasons stated earlier, Defendants disclosed the NISS investigation and had no duty to disclose it earlier in time. The alleged omissions based on the NISS investigation are therefore not actionable. *Shemian*, 2013 WL 1285779, at *20.

B. The Challenged Misrepresentations Are Not Actionable As A Matter of Law

Truthful And Optimistic Statements About The Noncirrhotic NASH NDA. Plaintiffs claim that statements discussing Intercept’s submission of the noncirrhotic NASH NDA and its anticipated approval were misleading. These statements include, for example (emphases added):

- “***Our submission of the first NDA*** for the treatment of fibrosis due to NASH is a ***very important milestone*** for the field and the culmination of more than a decade of hard work” (Ex. 3 (Sept. 27, 2019 Press Release) at 1; FAC ¶ 80.)
- “During the third quarter, ***we submitted our NDA seeking accelerated approval*** of OCA for NASH in the U.S., ***a historic achievement*** for our company and a ***critically important milestone*** for the many patients currently without an approved treatment” (Ex. 25 (Nov. 5, 2019 Press Release) at 1; FAC ¶ 82.)
- “Let me begin my summary of the quarter by noting the ***achievement of historic milestone with our submission of the first new drug application for NASH*** to the FDA ***Following its anticipated approval***, OCA is positioned to become the foundational therapy in patients with advanced fibrosis due to NASH.” (Ex. 26 (Nov. 5, 2019 Call Tr.) at 4-5; FAC ¶ 83.)
- “***If approved***, OCA would be the first available therapy for patients with fibrosis due to NASH [i]t is ***exciting to achieve this critical regulatory milestone*** that brings us one step closer to ***our goal*** of delivering the first approved therapeutic to those

living with this devastating disease.” (Ex. 27 (Nov. 25, 2019 Press Release) at 1; FAC ¶ 89.)

- “*Of course, our Phase III results set the stage for the submission of our NDA*, now under priority review by the FDA, with *anticipated approval* and launch within the first half of this year.” (Ex. 28 (Feb. 25, 2020 Call Tr.) at 4; FAC ¶ 92.)
- “*We remain very focused on the goal* of bringing the first approved therapy to patients with advanced fibrosis due to NASH” (Ex. 29 (May 11, 2020 Press Release) at 1; FAC ¶ 97.)
- “*We remain confident* in our NDA submission and *look forward to continuing to work with the FDA* to bring the first treatment to patients with advanced fibrosis due to NASH.” (Ex. 4 (May 22, 2020 Press Release), at 1; FAC ¶ 103.)

First, Defendants’ statements that they submitted an NDA for noncirrhotic NASH and that the NDA was under priority review are all accurate statements of objective historical facts and not misleading.²⁶ *Second*, in context, Defendants’ statements expressing their excitement about achieving an historical milestone of having submitted the first-accepted NDA for noncirrhotic NASH, and their cautious optimism that, “if approved,” Intercept would bring to market the first approved therapy for noncirrhotic NASH patients, are precisely the sort of statements reflecting “corporate optimism” that provide no objectively verifiable facts on which a reasonable investor would rely and thus cannot “give rise to securities violations.” *Kleinman*, 706 F.3d at 153; *In re Sanofi Sec. Litig.*, 87 F. Supp. 3d 510, 531 (S.D.N.Y. 2015) (statements expressing company’s expectation that FDA would approve drug were not actionable “absent concretely pled facts” to the contrary), *aff’d sub nom.*, *Tongue v. Sanofi*, 816 F.3d 199 (2d Cir. 2016); *In re Amarin Corp. PLC Sec. Litig.*, 689 F. App’x 124, 132 (3d Cir. 2017) (optimistic projections about FDA approval were nonactionable).

²⁶ *Fort Worth Emps.’ Ret. Fund v. Biovail Corp.*, 615 F. Supp. 2d 218, 230 (S.D.N.Y. 2009) (statements about FDA’s acceptance of application were nonactionable recitations of fact).

Opinion Statements About Ocaliva's Benefit-Risk Profile And PBC Business.

Plaintiffs also point to several opinion statements discussing Ocaliva's benefit-risk profile. (FAC ¶¶ 84, 92, 98, 106-07.) Opinions are actionable only if accompanied by allegations that (1) "the speaker did not hold the belief she professed," (2) "the supporting fact[s] [Defendants] supplied were untrue," or (3) the stated opinion "omit[ted] information whose omission ma[de] the [stated opinion] misleading to a reasonable investor." *Chapman v. Mueller Water Prods., Inc.*, 466 F. Supp. 3d 382, 398 (S.D.N.Y. 2020) (dismissing securities fraud claims).

Here, Dr. Pruzanski's statements in response to questions about the benefit-risk profile of Ocaliva in noncirrhotic NASH and PBC patients are all nonactionable statements of opinion:

- "[W]e're ***obviously very confident, based on all the data that we've seen***, in the favorable benefit-risk profile of OCA at the 25-milligram dose . . ." (FAC ¶ 84);
- "And it was ***gratifying to report*** 5-plus year treatment data demonstrating ***durable safety and efficacy*** . . . while exceeding 10,000 patient years of experience in the PBC population (FAC ¶ 92);
- "***[T]he safety topics that are well-known with respect to our drug*** that are in the literature" including "hepatic or more broadly hepatobiliary. . . ." (FAC ¶ 98);
- "***I don't think*** that there is anything" "substantively new in terms of safety issues [that have] arisen" and "***from our point of view***, nothing that stands out as a showstopper" (FAC ¶¶ 106-07); and
- We "***continue to believe*** that OCA has the potential to become the foundational treatment" for noncirrhotic NASH patients and "the enormous value, ***I think***, of our foundational business and PBC." (FAC ¶¶ 109-110.)²⁷

Plaintiffs have not shown (and cannot show) that these opinions were unfounded or somehow rendered misleading by the alleged failure to disclose the occurrence of certain liver-

²⁷ Plaintiffs also point to a statement made by Jerry Durso, Intercept's current CEO and then COO (*but not a defendant in this action*) that "we still, again, ***feel*** we have a significant opportunity yet in the PBC" business as allegedly misleading. (FAC ¶ 111.) Mr. Durso's nonactionable opinion statement cannot form the basis of a claim against the Defendants.

related SAEs—most of which were already on Ocaliva’s label and not unexpected—that occurred in about 1% of the PBC population. In any event, Plaintiffs’ allegations, *at most*, amount to a contention that the FDA ultimately disagreed with Intercept’s reasonable interpretation of Ocaliva’s known safety issues, but such later disagreements cannot form the basis of a securities fraud claim “because [r]easonable persons may disagree over how to analyze data and interpret results, and neither lends itself to objective conclusions.” *In re Sanofi*, 87 F. Supp. 3d at 543-44; *Kleinman*, 706 F.3d at 154 (finding drug company’s statement about data not actionable where there was no evidence company’s “interpretation of data” was unreasonable).

Accurate Risk Factor Statements. Plaintiffs allege that three statements in Intercept’s risk factors in its 3Q 2019 10-Q, 2019 10-K and 1Q 2020 10-Q, which were all filed *before* the May 2020 NISS investigation and the June 2020 CRL, were misleading:

- (1) “We remain focused on the safety of all of the patients using Ocaliva within and outside of our ongoing clinical studies[;]”
- (2) “These events and any safety concerns associated with Ocaliva, perceived or real, may adversely affect the successful development and commercialization of our product candidates and lead to a loss of revenues” or “our financial condition and results of operations[;]” and
- (3) “If new side effects are found, if known side effects are shown to be more severe than previously observed or if OCA is shown to have other unexpected characteristics, we may need to abandon our development of OCA for PBC, NASH and other potential indications. Furthermore, our commercial sales of Ocaliva for PBC may be materially and adversely affected.” (Ex. 30 (Q3 2019 10-Q) at 52, 54; Ex. 31 (2019 10-K) at 46, 48; Ex. 32 (Q1 2020 10-Q) at 52-53; FAC ¶¶ 85-87, 93-95, 99-101.)

But these risk factor disclosures—which warned investors of the very risks that Plaintiffs claim were hidden—were accurate at the time of the SEC filings *and remained accurate during the entire Class Period*. Plaintiffs do not allege any facts showing that the allegedly omitted SAEs had affected Ocaliva’s sales or revenue or that they caused Intercept to abandon Ocaliva for the treatment of NASH; to the contrary, Intercept continues to work with the FDA for

resubmission of the NDA. And at the time of these risk disclosures, the FDA had not taken any negative regulatory action that would support a claim that these risks had already materialized.

Singh v. Cigna Corp., 277 F. Supp. 3d 291, 315 (D. Conn. 2017), *aff'd*, 918 F.3d 57 (2d Cir. 2019) (risk warning that government action could have material adverse effect on business was not misleading because, at the time of the warnings, government's actions were immaterial).

III. PLAINTIFFS FAIL TO ADEQUATELY ALLEGE LOSS CAUSATION

Plaintiffs also fail to adequately allege loss causation. Plaintiffs have the burden to allege either (a) ““the existence of cause-in-fact on the ground that the market reacted negatively to a corrective disclosure of the fraud”” or (b) ““that the loss was foreseeable and caused by the materialization of the risk concealed by the fraudulent statement.”” *Sanofi*, 155 F. Supp. 3d at 409. Plaintiffs fail to meet either requirement.

As to the first two stock price declines, Plaintiffs allege that the May 22, 2020 press release disclosing the postponed AdCom and the June 29, 2020 press release disclosing the CRL were “materialization[s] of a known risk” because Defendants failed to disclose the NISS investigation, which raised a material risk that the NDA would not be approved. (FAC ¶¶ 115-120.) As shown above, however, Plaintiffs utterly fail to allege any facts connecting the FDA’s decisions to postpone the AdCom and issue the CRL for the *noncirrhotic NASH* NDA to its independent NISS investigation in *PBC* patients with advanced *cirrhosis*. Because Plaintiffs fails to plead a plausible “causal connection” between the two, “a fraud claim will not lie.” *Sanofi*, 155 F. Supp. 3d at 410 (granting motion to dismiss; rejecting loss causation allegations).

As to the third stock price decline, Plaintiffs allege that the October 8, 2020 STAT news article was a partial corrective disclosure because it “revealed” the NISS investigation. (FAC ¶¶ 121-23.) The STAT news article did not “reveal” the NISS investigation—Defendants had already disclosed it *two months earlier* (*supra* at 20). A news article containing already-public

information does not constitute a “corrective” disclosure unless there is materially new information included in the disclosure. *Cent. States, Se. & Sw. Areas Pension Fund v. Fed. Home Loan Mortg. Corp.*, 543 F. App'x 72, 75 (2d Cir. 2013). The STAT news article’s purely speculative questioning about whether the NISS investigation contributed to the FDA’s decisions on the noncirrhotic NASH NDA was not “new” information. *Janbay v. Canadian Solar, Inc.*, No. 10-Civ-4430 (RWS), 2012 WL 1080306, at *16 (S.D.N.Y. Mar. 30, 2012) (rejecting loss causation allegations in part because the “the raising of questions and speculation by analysts and commentators does not reveal any ‘truth’ about an alleged fraud”).

IV. COUNT II ALLEGING CONTROL PERSON LIABILITY SHOULD BE DISMISSED

Plaintiffs’ Section 20(a) claim alleging control liability (FAC ¶¶ 169-173) should be dismissed because Plaintiffs fail to plead a primary violation of Section 10(b). *Chapman*, 466 F. Supp. 3d at 414.

CONCLUSION

Defendants’ motion to dismiss should be granted and the First Amended Complaint should be dismissed with prejudice.

Dated: New York, New York
April 26, 2021

James R. Carroll (*pro hac vice*)
Alisha Q. Nanda
Rene H. DuBois
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
500 Boylston Street
Boston, Massachusetts 02116
Telephone: (617) 573-4800
james.carroll@skadden.com
alisha.nanda@skadden.com
rene.dubois@skadden.com

Respectfully submitted,

/s/ Scott D. Musoff

Scott D. Musoff (scott.musoff@skadden.com)
SKADDEN, ARPS, SLATE,
MEAGHER & FLOM LLP
One Manhattan West
New York, New York 10001
Telephone: (212) 735-3000

*Attorneys for Defendants
Intercept Pharmaceuticals, Inc.,
Mark Pruzanski, and Sandip S. Kapadia*